

APPENDIX L

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Monday, November 28, 2005

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Lung Cancer

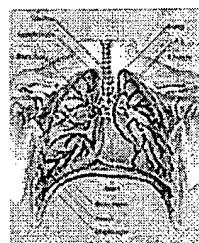
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A person is assigned a clinical "stage" of lung cancer after undergoing a diagnostic work-up. Staging describes the extent of disease. It is based on a pathology (disease) report from tissue obtained during bronchoscopy, needle (or other) biopsy, blood work, and imaging studies to rule out distant metastases. Imaging studies include chest X-ray, abdominal ultrasound (images produced by high-frequency sound waves) of the liver, radionuclide (radioactive atom-based) bone scans, and CT or CAT scan (computer-assisted technique that produces cross-sectional images of the body) or magnetic resonance imaging (MRI) of the brain, chest, and abdomen. Staging is complete when a patient has undergone surgical pathology and imaging studies. The physician then uses all available information to determine the stage that best describes the patient's condition.

Lung cancer staging helps the physician to determine how a patient will do over the long term. It distinguishes people with limited disease from those with distant metastases. Staging provides an estimate of disease-free survival, overall survival, and risk of cancer recurrence or relapse. Staging also helps the physician to choose appropriate treatment for each patient. The influence of staging is particularly important when radiation or surgical therapy are added to chemotherapy in treating patients with limited stage disease.

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Lung cancer staging usually is described in terms of the TNM system - a classification system developed and recently revised by the American Joint Committee on Cancer (AJCC) and the Union Internationale Contre le Cancer (UICC; International Union Against Cancer). According to this system:

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- T = tumor size
- N = node involvement
- M = metastasis status

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Lung cancer treatment ultimately depends upon such staging. In general, the lower the stage, the more favorable is the individual's prognosis.

Tumors

The primary tumor (T) is classified according to the following categories:

- TX: Tumor cannot be evaluated or tumor is proven by the presence of cancer cells in the sputum or bronchial washings, but it cannot be seen during imaging or bronchoscopy ("occult" tumor)
- T0: No evidence of primary tumor
- Tis: Carcinoma in situ
- T1: Tumor 3 centimeters (< 3 cm) or less in greatest dimension, surrounded by lung or pleura, and not located in the main stem bronchus
- T2: Tumor more than 3 centimeters (> 3 cm) in greatest dimension, or tumor involving the main stem bronchus, 2 cm or more from the carina, or tumor invading the visceral pleura, or tumor with incomplete lung expansion or obstructive lung infection that does not involve the entire lung
- T3: Tumor of any size that directly invades the chest wall, diaphragm, pleura, or pericardium, or tumor that involves the main stem bronchus less than 2 centimeters (< 2 cm) from the carina (ridge between the right and left main stem bronchi), or tumor that is associated with complete lung collapse or obstructive lung infection involving the entire lung.
- T4: Tumor of any size that invades the heart, great vessels (aorta, superior or inferior vena cava, pulmonary artery, or pulmonary vein), trachea, esophagus, vertebral body, or carina, or separate tumor nodules in the same lung lobe, or tumor associated with a malignant pleural effusion.

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The regional lymph nodes (N) are clinically divided into the following categories:

NX: Regional lymph nodes cannot be assessed

NO: Regional lymph nodes contain no metastases

N1: Metastasis to same-side peribronchial (around the bronchi) and/or hilar (pit in the lungs where vessels enter and exit) lymph nodes and nodes within the lungs that are involved by direct spread of the primary tumor

N2: Metastasis to same-side mediastinal and/or subcarinal (under the carina, or tracheal ridge) lymph nodes.

N3: Metastasis to opposite-side mediastinal or hilar nodes or to same- or opposite-side scalene (neck/upper rib) or supravacuicular (above collarbone) lymph nodes.

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The state of metastasis (M) is defined as follows:

MX: Distant metastases cannot be assessed

M0: No distant metastases are found

M1: Distant metastases are present (this also includes separate tumor nodules in a different lobe of lung on either side).

Staging

The TNM system - which includes the overall features of the tumor, lymph nodes, and metastatic status - places lung cancer growth at a particular stage. Apart from "occult - hidden yet to be identified tumors (occult: txn0m0) and confined carcinomas *in situ* (stage 0: tis) there are four basic stages within the TNM classification system:

Stage Ia: T1, N0, M0

Stage Ib: T2, N0, M0

Stage IIA: N1, M0

Stage IIB: T2, N1, M0 or T3, N0, M0

Stage IIIa: T1-2, N2, M0 or T3, N1-2, M0

Stage IIIb: T(any), N3, M0 or T4, N(any), M0

Stage IV: T(any), N(any), M1

The TNM staging system is not often used for patients with small cell lung carcinoma (SCLC), because most have suspected or definite metastatic disease at the time of diagnosis. Survival in such individuals usually is unaffected by minor differences in the extent of tumor involvement. Instead, most experts use a simple, two-stage system created by the Veterans Administration Lung Cancer Study Group. This system defines SCLC as being of "limited" or "extensive" stage.

Although this system has not been universally accepted, according to many experts limited-stage SCLCs are lung cancers that are confined to one side of the chest, the mediastinum (tissues and organs of the middle chest, e.g., the heart and large vessels, windpipe, etc.), and the supraclavicular (above-collarbone) nodes. Such SCLCs can be enclosed within a tolerable radiation therapy port. Patients with pleural effusion, very large tumors, and opposite-side supraclavicular nodes may or may not be included within this category.

Extensive-stage SCLCs are lung cancers that are too widespread to be considered limited stage. All individuals with distant metastases are placed in this category.

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